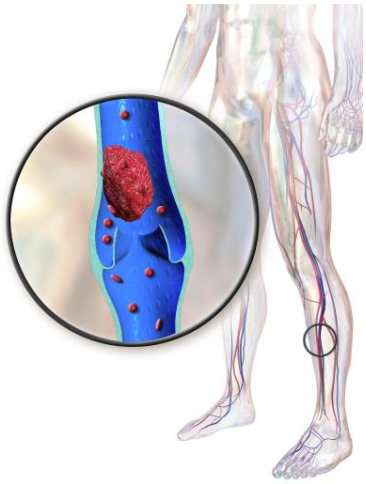
ATTACHMENT D

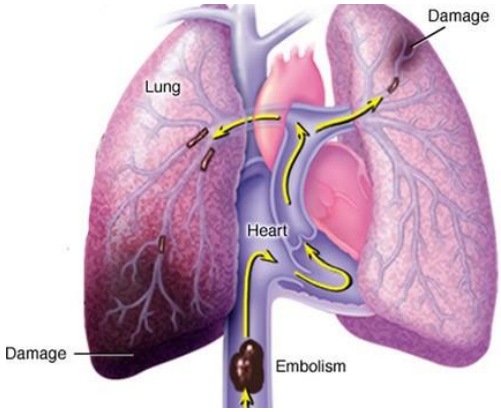
I. FACTUAL BACKGROUND

A. The Bard Recovery Filter

The Recovery filter and other IVC filters are designed to prevent large blood clots that form in the deep veins of the human body (i.e., DVTs) from migrating to the heart or lungs and precipitating a PE, a well-recognized and leading cause of sudden death. The following are illustrations of a DVT and PE:



Deep Vein Thrombosis

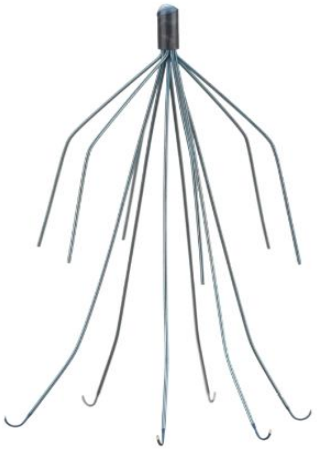


Pulmonary Embolism

Although IVC filters provide protection from potentially life-threatening events (i.e., PE), they also carry certain well-known risks. The risks of filter tilt, fracture, embolization of fractured portions of the filter, and perforation of the IVC, among other complications, are well known in the medical community to occur in all types of IVC filters.

The Recovery filter is Bard's first generation retrievable IVC filter[1] and was cleared by FDA for retrievable use in 2003. Unlike other IVC filters then on the market, the Recovery filter could be retrieved months or even years after implant, typically after the risk of PE had passed for the patient.

The Recovery filter consists of two tiers of struts that make up its "arms" and "legs."



The Recovery filter is placed in the IVC using a catheter via a small puncture in the femoral vein located in the groin, as was the case for Plaintiff, or the jugular vein located in the neck. Once the filter is deployed, its arms and legs open and anchor it in the walls of the IVC. The IVC filter then helps to catch blood clots, also known as DVTs, that originate in the lower part of the body and could otherwise migrate into the heart or lungs and cause a PE.

[1] Bard stopped marketing the Recovery filter in 2005. Since then, based partly on its clinical experience with the Recovery filter, Bard has designed and marketed six successive generations of retrievable filters. These filters differ in many respects. Bard's latest retrievable filter, the Denali filter, has remained on the market since 2013.

Before Bard could market any of its IVC filters, which are regulated by FDA as "Class II" devices, federal law required Bard to obtain FDA clearance through section 510(k) of the Medical Device Amendments of 1976 ("MDA"), which amended the Food, Drug, and Cosmetic Act ("FDCA"). FDA will clear a Class II medical device only if it determines that the device is "substantially equivalent" to a predicate device.[2] As amended by the Safe Medical Devices Act ("SMDA") of 1990, section 510(k) requires that a device, such as the Recovery filter, is "substantially equivalent" only if the FDA determines that it has the "same technological characteristics" of a predicate device, or receives data demonstrating that "the device *is as safe and as effective* as a legally marketed device" and any technological differences "do not raise *different questions of safety and effectiveness*." 21 U.S.C. § 360c(i)(A) (emphasis added); 21 C.F.R. § 807.100(b).

For the Recovery filter, FDA required, among other things, clinical testing, and extensive in vitro and biocompatibility testing. Following review of the 510(k), FDA mandated specific revisions to the labeling, as well as additional information in response to specific safety and effectiveness questions regarding the clinical, in vitro, and biocompatibility testing and other data.

[2] A "predicate device" is a device that was legally marketed prior to May 28, 1976, a device which has been reclassified from Class III to Class II or Class I, or a device which has been previously found substantially equivalent through the 510(k) process. 21 C.F.R. § 807.92(a)(3).

Bard filed its 510(k) premarket notification for the Recovery filter as a permanent filter on July 10, 2002. Before FDA would clear the Recovery filter, it required Bard to provide additional information and detailed responses to 17 separate questions, many involving safety and effectiveness concerns. Bard provided detailed data in response to the FDA's multiple requests. FDA also required Bard to revise the Recovery filter IFU and labeling to reflect that the filter was for permanent placement only, which Bard did. FDA cleared the device after determining that it was as safe and effective as, and therefore substantially equivalent to, the predicate device. *See* 21 U.S.C. § 360c(i)(A). But FDA placed a limitation on the substantial equivalence determination, requiring specific language in the labeling warning that "the safety and effectiveness of the Recovery filter for use as a retrievable or temporary filter have not been established."

Before Bard's Recovery filter could be cleared for a retrievable indication, FDA required Bard to submit clinical data supporting the safety and effectiveness of retrievability. Accordingly, a clinical study regarding retrievability of the Recovery filter was conducted, and, on April 25, 2003, BPV submitted that clinical data with a new 510(k) submission. FDA reviewed the new submission and again determined that it needed additional information and required further revisions to the labeling

before it would clear the device. Bard complied with each request. On July 25, 2003, FDA cleared the Recovery filter as a retrievable device and removed the limitation.[3]

B. Plaintiff's Medical Course and Discovery of her Alleged Filter Complications.

Plaintiff Jennifer Coker has an extensive medical history and many significant medical conditions, including Factor V Leiden, a genetic blood-clotting disorder, paralyzed left diaphragm, morbid obesity, thyroid disorder, degenerative disc disease, hypertension, and fibromyalgia.

In 2003, Mrs. Coker presented to the hospital pregnant and complaining of upper abdominal pain. She was diagnosed with bilateral PE. Later that year, an evaluation by a pulmonologist documented sporadic chest pain and shortness of breath, and a few months later Mrs. Coker was again evaluated for recurrent chest pain.

In September 2004, Mrs. Coker presented to Kennestone Hospital for another evaluation of shortness of breath and was diagnosed with another PE. She was treated with heparin and started on warfarin, an anticoagulation medication to help prevent blood clots.

The following day, Mrs. Coker presented to Northside Hospital still

[3] FDA was already heavily involved in revising the labeling before the second 510(k). Post-marketing, FDA was heavily involved in post-market revisions of the labeling and a Dear Doctor Letter that Bard planned to send, as well as post-market review of a Dear Colleague Letter.

complaining of shortness of breath, and a CT of the chest showed PE now affecting both lungs. Plaintiff's bilateral PE was attributed to a combination of smoking, obesity, and Factor V Leiden (a genetic blood-clotting disorder). Because of the finding of a new PE in the left lung, an IVC filter was prescribed by Dr. Stephanie Eaton.

On September 27, 2004, Dr. Jason Levy implanted a Recovery® Filter in Mrs. Coker's IVC. Before implanting the Filter, Dr. Levy determined that the benefits of the Filter outweighed its risks and determined that placement of a Recovery Filter in Mrs. Coker was indicated and appropriate. Dr. Levy was aware of the risks of IVC filters, but does not recall reading the Instructions for Use that accompanied the filter.

Before the implant procedure, Mrs. Coker signed an informed consent form for the Filter placement acknowledging that she was informed of the complications and risks involved in the procedure and that no guarantees were made concerning the results of the procedure. After obtaining written, informed consent from Mrs. Coker, Dr. Levy successfully implanted the Filter.

After the implant, Mrs. Coker' s medical course remained complicated. She alleges that the filter perforated her inferior vena cava and fractured causing her pain and suffering. Bard acknowledges that the filter perforated her IVC, and fractured, but denies that those events were the proximate cause of Ms. Coker's alleged

symptoms or claimed damages.

Bard denies that the product at issue was defective in design or warning, that Bard was negligent or that the product or any actions of Bard were the proximate cause of the injuries that Plaintiff alleges. Bard further denies that there is any evidence to warrant a claim for punitive damages.

II. RELEVANT RULES, REGULATIONS, STATUTES, ORDINANCES, AND CASE LAW

a. Strict Liability (General Aspects)

To recover, the person injured by an allegedly defective product must establish that (a) the product was defective, (b) the defect existed at the time the product left the manufacturer's control, and (c) the defect in the product was the proximate cause of the person's injury. *See* O.C.G.A § 51-1-11; *Banks v. ICI Americas, Inc.*, 450 S.E.2d 671 (Ga. 1994); *SK Hand Tool Corp. v. Lowman*, 479 S.E.2d 103 (1996) (en banc); *Ellis v. Rich's, Inc.*, 212 S.E.2d 373 (Ga. 1975); *Orkin Exterminating Co., Inc. v. Dawn Food Products*, 366 S.E.2d 792 (Ga. App. 1988); Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.610.

b. Failure to Warn (Negligent and Strict Liability)

Bard denies that its warning was defective or that it was negligent in warning the implanting doctor about the risks of the filter.

To establish a failure to warn claim under Georgia law, "the plaintiff must show the defendant had a duty to warn, the defendant breached that duty and the

breach was the proximate cause of the plaintiff's injury." *Wheat v. Sofamor, S.N.C.*, 46 F. Supp. 2d 1351, 1362 (N.D. Ga. 1999).

In cases involving medical devices, Georgia applies the "learned intermediary" doctrine. Under this doctrine, the manufacturer has no "duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and manufacturer." *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) (citing *Ellis v. C. R. Bard, Inc.*, 311 F.3d 1272, 1279-80 (11th Cir. 2002)). The manufacturer's warnings to the physician, however, "must be adequate or reasonable under the circumstances of the case." *Id*. In addition, where a product is sold to a particular group or profession, the manufacturer is not required to warn against risks generally known to such group or profession. *Exxon Corporation v. Jones*, 433 S.E.2d 350, 353 (Ga. Ct. App. 1993).

Causation on a failure to warn claim cannot be established if the implanting physician did not read the warning. In *In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 711 F. Supp.2d 1348, 1378 (M.D. Ga. 2010). *Henry v. General Motors Corp.*, 60 F.3d 1545, 1548 (11th Cir. 1995) ("[u]nder Georgia law, a product user's failure to read an allegedly negligent warning, not the warning itself, is considered the proximate cause of an injury")

"Manufacturers are not insurers, and a manufacturer cannot be held liable for a consumer's failure to read or to listen to understandable warnings." *Walker v. Merck & Co.*, 648 F. Supp. 931, 935-36 (M.D. Ga. 1986) (plaintiff signed vaccine consent form with warnings, but did not read it). A New Jersey appellate court, applying Georgia law, has held that "the doctor's decision to not read the manufacturer's warnings . . . does not alter his learned intermediary role nor does it impose liability on defendants for failure to warn." *Goodson v. C.R. Bard & Davol, Inc.*, 2018 WL 1370652, at *6 (N.J. Super. Ct. App. Div. March 19, 2018).

c. Design Defect (Negligent and Strict Liability)

Defendants contend that the benefits of the filter to Ms. Coker outweighed inherent risks of the Bard Recovery filter and all IVC filters.

Georgia the uses a "risk-utility" test for product liability claims. *Banks*, 450 S.E.2d at 674. "A product may be found defective because of its particular design. Although a manufacturer is not required to ensure that a product design is incapable of producing injury, the manufacturer has a duty to exercise reasonable care in choosing the design for a product." Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.640.

To determine whether a product suffers from a design defect, there must be a balancing of the inherit risk of harm in a product design against the utility or benefits

of that product design. There must be a determination whether the manufacturer acted reasonably in choosing a particular product design by considering all relevant evidence, including, but not limited to, the following factors:

- the usefulness of the product;
- the severity of the danger posed by the design;
- the likelihood of that danger;
- the avoidability of the danger, considering the user's knowledge of the product, publicity surrounding the danger, the effectiveness of warnings, and common knowledge or the expectation of danger;
- the user's ability to avoid the danger;
- technology available when the product was manufactured;
- the ability to eliminate danger without impairing the usefulness of the product or making it too expensive;
- the feasibility of spreading any increased cost through product's price or by purchasing insurance;
- the appearance and aesthetic attractiveness of the product;
- the product's utility for multiple uses;
- the convenience and durability of the product;
- alternative designs for the product available to the manufacturer;
- and the manufacturer's compliance with the industry standards and

government regulations.

Banks, 450 S.E.2d at 675 n. 6, Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.650.

Bard contends that Plaintiff cannot provide evidence of a safer alternative design available at the time Ms. Coker's filter was implanted. In determining whether a product was defective, the jury may consider evidence of alternative designs that would have made the product safer and could have prevented or minimized the plaintiff's injury. In determining the reasonableness of the manufacturer's choice of product design, the jury should consider 1) the availability of an alternative design at the time the manufacturer designed this product; 2) the level of safety from an alternative design compared to the actual design; 3) the feasibility of an alternative design, considering the market and technology at the time the product was designed; 4) the economic feasibility of an alternative design; 5) the effect an alternative design would have on the product's appearance and utility for multiple purposes; and 6) any adverse effects on the manufacturer or the product from using an alternative design. Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.660.

Bard contends that it complied with all FDA regulations applicable to the filter, specifically Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.* and Section 510(k) of the Food, Drug, and Cosmetic Act.

In determining whether a product was defective, the jury may consider proof of a manufacturer's compliance with federal or state safety standards or regulations and industrywide customs, practices, or design standards. Compliance with such standards or regulations is a factor to consider in deciding whether the product design selected was reasonable considering the feasible choices of which the manufacturer knew or should have known. However, a product may comply with such standards or regulations and still contain a design defect. Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.670.

d. Punitive Damages

Bard contends there is no evidence that warrants punitive damages. Under Georgia law, punitive damages may only be awarded when "it is shown by clear and convincing evidence that the defendant's actions showed willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care which would raise the presumption of conscious indifference to consequences." Ga. Code Ann. § 51-12-5.1(b).

Under the conscious indifference standard, "punitive damages are available where a manufacturer knows that its product is potentially dangerous and chooses to do nothing to make it safer or to warn consumers." *Cisson*, 2013 WL 5700513, at *13 (citations omitted).

Punitive damages are awarded not as compensation to a plaintiff but solely to punish, penalize or deter a defendant. *See* O.C.G.A. §51-12-5.1(b),(c); Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 66.700, 66.702.

e. List of Authorities

Bard will rely upon the following relevant rules, regulations, statutes, ordinances, and case law:

Case Law

Banks v. ICI Americas, Inc., 450 S.E.2d 671 (Ga. 1994)
SK Hand Tool Corp. v. Lowman, 479 S.E.2d 103 (1996) (en banc)
Dietz v. Smithkline Beecham Corp., 598 F.3d 812 (11th Cir. 2010)
Thornton v. E.I. Du Pont De Nemours & Co., *Inc.*, 22 F.3d 284 (11th Cir. 1994)
Dozier Crane & Machinery, Inc. v. Gibson, 644 S.E.2d 333 (Ga. App. 2007)
Camden Oil Co., LLC v. Jackson, 609 S.E.2d 356 (Ga. App. 2004)
In re Cook Medical, Inc. IVC Filters Marketing, Sales Practices & Products Liability Litigation, 2018 WL 6415585 (S.D. Ind. Dec. 5, 2018) (applying Georgia law)
Russell v. Ethicon, Inc., No. 4:20-CV-00405, 2020 WL 5993774 (M.D. Pa. Oct. 9, 2020)
Castillo v. Boston Scientific Corp., 2020 WL 2771193 (W.D. Tex. May 28, 2020)
In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation, 711 F. Supp.2d 1348 (M.D. Ga. 2010)
Watkins v. Ford Motor Co., 190 F.3d 1213 (11th Cir. 1999)
McCombs v. Synthes (U.S.A.), 587 S.E.2d 594 (Ga. 2003)
Wheat v. Sofamor, S.N.C., 46 F. Supp. 2d 1351 (N.D. Ga. 1999)
Wheeler v. Novartis Pharms. Corp., 944 F. Supp. 2d 1344 (S.D. Ga. 2013)
Lance v. Am. Edwards Labs., 452 S.E.2d 185 (Ga. Ct. App. 1994)
Hawkins v. Richardson-Merrell, Inc., 249 S.E.2d 286 (Ga. Ct. App. 1978) (en banc)
Catlett v. Wyeth, Inc., 379 F. Supp. 2d 1374 (M.D. Ga. 2004
Ellis v. C.R. Bard, Inc., 311 F.3d 1272 (11th Cir. 2002)
Porter v. Eli Lilly & Co., 2008 WL 544739, *9-12 (N.D. Ga. Feb. 25, 2008), *aff'd*, 291 F. App'x 963 (11th Cir. 2008)
Presto v. Sandoz Pharm. Corp., 487 S.E.2d 70 (Ga. Ct. App. 1997)

Chrysler Corp. v. Batten, 450 S.E.2d 208 (Ga. 1994)
Exxon Corporation v. Jones, 433 S.E.2d 350 (Ga. Ct. App. 1993)
Watkins v. Eli Lilly & Co., No. 1:08-CV-1665, 2010 WL 11493785 (N.D. Ga. Mar. 31, 2010)
Bodymasters Sports Indus., Inc. v. Wimberley, 501 S.E.2d 556 (Ga. Ct. App. 1998)
Roberts v. Forte Hotels, Inc., 489 S.E.2d 540 (Ga. Ct. App. 1997)
COMCAST Corp. v. Warren, 650 S.E.2d 307 (Ga. Ct. App. 2007)
Stone Man, Inc. v. Green, 435 S.E.2d 205 (Ga. 1993)
Barger v. Garden Way, Inc., 499 S.E.2d 737 (Ga. Ct. App. 1998)
Edwards v. Ethicon, Inc., 30 F. Supp. 3d 554 (S.D. W. Va. 2014) (applying Georgia law)
Mack Trucks, Inc. v. Conkle, 436 S.E.2d 635 (Ga. 1993)
In re Bard IVC Filters Prod. Liab. Litig., No. 18-16349, 2020 WL 4692349 ("*Booker*")
In re Bard IVC Filters Prod. Liab. Litig., No. 18-16349, 2020 WL 4692349 ("*Jones*")
Orkin Exterminating Co., Inc. v. Dawn Food Products, 366 S.E.2d 792 (Ga. App. 1988)
Davis v. Glaze, 354 S.E.2d 845 (Ga. 1987)
Smokey Mountain Enterprises, Inc. v. Bennett, 359 S.E.2d 366 (Ga. App. 1987)
BMW of No. America v. Gore, 517 U.S. 559 (1996)
State Farm Mut. Auto Ins. Co. v. Campbell, 123 S. Ct. 1513 (2003)
Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2001)
Johansen v. Combustion Eng'g, Inc., 170 F.3d 1320, 1333 (11th Cir. 1999).
Philip Morris USA v. Williams, 549 U.S. 346, 353 (2007)
Dimaso v. Ford Motor Company, et. al., No. 99-A-6172-6, 2003 WL 22850075, at *1 (Ga. Super. 2003)
Hockensmith v. Ford Motor Co., No. 1:01-CV-3645G, 2003 WL 25639639, at *10 (N.D. Ga. Apr. 17, 2003)

Statutes

O.C.G.A § 51-1-11
O.C.G.A.§ 51-1-12
O.C.G.A. § 51-12-5.1(b),(c)
O.C.G.A. § 51-12-5.1 (e)(1)

Regulations

Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq*.

Section 510(k) of the Food, Drug, and Cosmetic Act

Rules

Federal Rules of Evidence
Federal Rules of Civil Procedure

Constitution

Constitution of the United States of America (Forth, Fifth, Sixth, Eighth, Fourteenth)
Georgia Constitution

Other Authority

Order and Suggestion of Remand [Dkt. 74-1]
Restatement (Second) of Torts, § 402A and comments thereto
Restatement (Third) of Torts (Products Liability) and comments thereto
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.610
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 60.010
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.640
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.650
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.670
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 62.660
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 66.700
Council of Superior Court Judges' Suggested Pattern Civil Jury Instructions, 66.702
Eleventh Circuit Suggested Pattern Civil Jury Instructions